Section II. (REMARKS)

The pending claims are 1-9, 18, 19, 26 and 28-34.

Claims 1-9, 18, 19 and 26 have been amended herein, without prejudice. Claims 10-15, 17, 20-25, and 27 have been cancelled herein, without prejudice, and with the reservation of the right to file said claims and related subject matter in continuing and/or divisional applications.

Claims 28-34 are new.

No new matter has been added herein.

Claim Objection

Claim 21 was objected to because the claim does not end in a period (","). Applicants have cancelled claim 21 thereby obviating this objection.

Rejection of Claims and Transversal Thereof

In the July 31, 2008 Office Action:

- claims 1-9, 18-19, 21 and 25-26 were rejected under 35 U.S.C. §112, first paragraph; and
- claims 5-8 were rejected under 35 U.S.C. §112, second paragraph.

These rejections are respectfully traversed. The patentable distinctions of the pending claims over the cited references are set out in the ensuing discussion.

Rejections under 35 U.S.C. §112, first paragraph

In the July 31, 2008 Office Action, claims 1-9, 18-19, 21 and 25-26 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants traverse such rejection.

1. According to the Examiner, claims 1-9 were substantively amended and claims 18-19, 21, and 25-26 were newly introduced, however, no basis was pointed to for these changes and new claims. Support is provided herein thereby obviating this rejection.

Claim 1 has been amended to recite:

> **"A peptide comprising an amino acid sequence selected from SEQ ID NO:17, or between 9 and 14 consecutive amino acid residues of SEQ ID NO:17, and their pharmaceutically acceptable salts, wherein the peptide is characterized by a capacity to bind to transforming growth factor β1 (TGF-β1)."**

Support for the amendment to claim 1 includes the election of SEQ ID NO: 17, and the instant specification at page 7, lines 4-11. The limitation "characterized by a capacity to bind . . . TGF-β1" was in the preamble of the claim as filed and was moved to the body of the claim at the time of national phase filing.

Claim 2 has been amended herein to recite:

> **"The peptide according to claim 1, comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26, SEQ ID NO: 27, SEQ ID NO: 28, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 31, SEQ ID NO: 32, SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO: 35 and SEQ ID NO: 36."**

Support for the amendment to claim 2 can be found in the Examiner's acknowledgement that SEQ ID NOS: 24-36 should be rejoined upon allowance of SEQ ID NO:17 as well as the instant specification at page 7, lines 4-11.

Support for claims 3 and 26 can be found in claim 3 of the application as filed. Support for claim 4 can be found impliedly in claim 5 of the application as filed; page 10, lines 13-19; and page 11, lines 6-10. Support for claims 5-7 can be found in claims 7-9 of the application as filed. Support for claims 8 and 21 can be found in the instant specification at page 10, lines 13-15. Support for claim 9 can be found in claim 6 of the application as filed. Support for claim 18 and new claim 32 can be found in the instant specification at page 9, lines 21-23. Support for claim 19 and new claims 28-31 can be found in the instant specification at page 7, lines 4-11. Support for new claim 33 can be found in the instant specification at page 6, lines 19-28. Support for new claim 34 can be found in the instant specification at

page 6, lines 21-28.

2. According to the Examiner, claim 1 as previously amended includes truncations of one or two amino acids whereas the original claim recited fragments comprising 3 to 15 amino acids. Applicants have amended claim 1 as introduced hereinabove thereby obviating this rejection.

3. According to the Examiner, claim 2 as amended does not require a biological activity whereas the original claim recited inhibition of TGF-β1 *in vitro* and/or *in vivo* and new claim 26 adds this activity. In view of the fact that claim 26 adds this activity, it is unclear what the nature of the rejection is. Applicants respectfully request clarification.

4. According to the Examiner, the methods of claims 5-7 do not appear to be contemplated. Applicants vigorously disagree.

It is well established in the law that to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention at the time of filing. MPEP §2163 (I) (citing *Vas-Cath, Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991)). Furthermore, each claim must be given its broadest reasonable interpretation in light of and consistent with the written description. MPEP §2163 (II)(A)(1) (citing, *e.g.*, *In re Morris*, 44 U.S.P.Q.2d 1023, 1027 (Fed. Cir. 1997)).

Claim 7 of the application as filed recites:

> "Use of a peptide according to anyone of claims 1 to 4 <u>in the manufacture of</u> a pharmaceutical composition <u>for the treatment of diseases or pathological alterations associated with excessive or deregulated TGF-β1 expression</u>." (emphasis added)

Comparing claim 7 as filed with claim 5 pending herein, it can be seen that both relate to the method of making/manufacture of a pharmaceutical composition useful for the treatment of diseases and pathological alterations associated with excessive or deregulated expression of TGF-β1. Considering this disclosure in applicants' specification, one skilled in the art would reasonably conclude that the inventors had possession of the claimed invention at the time of filing and as such, the written description requirement was satisfied. Analogously, pending claims 6 and 7, which were amended to depend from claim 5, were disclosed in the instant specification at claims 8 and 9. As such, they also satisfy the

written description requirement. Withdrawal of the rejection of claims 5-7 is respectfully requested.

5. According to the Examiner, the specification does not appear to contemplate the composition of claim 8 in the absence of pharmaceutically acceptable excipient. Applicants have amended claim 8 thereby obviating this rejection.

6. According to the Examiner, the specification does not appear to contemplate the compositions of claim 9. Claim 9 has been amended to recite that the composition may further comprise one or more alternative TGF-β1 inhibiting compounds. Support for said amendment can be found in claim 6 of the application as filed.

7. According to the Examiner, the specification does not appear to contemplate the generic concept in claims 18 and 25 that SEQ ID NO:17 is truncated up to five amino acids from the C terminal end. Claim 18 has been amended to recite that SEQ ID NO:17 is truncated from its C-terminal end and claim 25 has been cancelled. Support for the amendment of claim 18 can be found in the instant specification at page 9, lines 21-23.

Considered *in toto*, applicants request withdrawal of the rejection of claims 1-9, 18, 19, 21, and 25-26 under 35 U.S.C. §112, first paragraph.

Rejections under 35 U.S.C. §112, second paragraph

In the July 31, 2008 Office Action, claims 5-8 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. Applicants traverse such rejection.

1. According to the Examiner, claims 5-7 are confusing because they do not provide further limitations to the steps for making the pharmaceutical composition.

Claim 5 defines a function of the pharmaceutical composition of claim 4. According to the MPEP, functional language does not, in and of itself, render a claim improper,[1] but rather must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary

[1] *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

skill in the pertinent art in the context in which it is used. MPEP 2173.05(g). In the present case, claim 5 does not convey to the skilled practitioner another step in the method of making but rather a further limitation of the pharmaceutical composition recited in claim 4 and as such, it is proper. Claims 6 and 7 have been amended herein to depend from claim 5 to further define the diseases recited in claim 5. Accordingly, claims 5-7 are definite and as such, satisfy 35 U.S.C. §112, second paragraph.

2. According to the Examiner, claim 7 is unclear because of the parentheses around cirrhosis. Applicants have amended claim 7 thereby obviating this rejection.

3. According to the Examiner, claim 8 does not further limit the peptide of claim 1. As introduced hereinabove, claim 8 has been amended to include the limitation of previously pending claim 21, thereby obviating this rejection.

Considered *in toto*, applicants request withdrawal of the rejection of claims 5-8 under 35 U.S.C. §112, second paragraph.

Petition for Extension of Time/Fees Payable

Applicants hereby petition for a one (1) month extension of time, extending the deadline for responding to the July 31, 2008 Office Action from October 31, 2008 to December 1, 2008 (November 30, 2008 is a Sunday). The fee of $130.00 specified in 37 CFR §1.17(a)(1) for such one (1) month extension is hereby enclosed.

Seven (7) claims have been added, two (2) of which is independent, and fourteen (14) claims have been cancelled herein, bringing the total number of pending claims to eighteen (18), three (3) of which are independent. As such, no added claims fee is due at this time.

The total fee of $130.00 is being paid by Electronic Funds Transfer. Authorization is hereby given to charge any deficiency in applicable fees for this response to Deposit Account No. 13-4365 of Moore & Van Allen PLLC.

Conclusion

Based on the foregoing, claims 1-9, 18, 19, 26 and 28-34 are in form and condition for allowance. If any additional issues remain, the Examiner is requested to contact the undersigned attorney at (919) 286-8000 to discuss same.

Respectfully submitted,

MOORE & VAN ALLEN PLLC

Date: December 1, 2008

By: _____

Tristan Anne Fuierer
Registration No. 52,926
Moore & Van Allen PLLC
430 Davis Drive, Suite 500
Morrisville, NC 27560-6832
Telephone: (919) 286-8000
Facsimile: (919) 286-8199